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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/913,788	08/15/2001	Roger Ariel Alberto	1292 WO/US	4148

7590 10/31/2003

Mallinckrodt Inc
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EXAMINER	
HUFF, SHEELA JITENDRA	
ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 10/31/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/913,788	ALBERTO ET AL.	
	Examin r	Art Unit	
	Sheela J Huff	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 October 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9-25* is/are pending in the application.

4a) Of the above claim(s) *9-21 23 24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22 and 25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Response to Amendment

The amendment filed on 10/16/03 has been considered. Applicant's arguments are deemed to be persuasive-in-part.

Claims 9-21, 23-24 are withdrawn from consideration as being drawn to a non-elected invention.

Claims 22 and 25 are currently under consideration.

The rejection of claim 22 under 35 U.S.C. 102(b) as being anticipated by Fawwaz et al, J. Nuclear Medicine, Proc. Of the 36th Annual Meeting, vol. 30 p. 935-936 (1989) is withdrawn in view of applicant's arguments.

The rejection of claims 25- under 35 U.S.C. 103(a) as being unpatentable over Fawwaz et al, J. Nuclear Medicine, Proc. Of the 36th Annual Meeting, vol. 30 p. 935-936 (1989) is withdrawn in view of applicant's arguments.

Response to Arguments

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 22 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 93/21957. In view of the newly added limitation, the rejection is re-written.

This reference discloses conjugates comprising a metal radionuclide ion(which can be Tc, Re and Mn) ,a complexing agent (which can be phenanthroline) and an immunoreactive group (which can be a variety of different antibodies, proteins, hormones etc) see pages 6, 8, 61-64. On page 9, the reference discloses that the compounds can be used in methods for diagnostic imaging and treating diseases.

The only difference between the reference and the instant invention, it that the reference does not specifically make the conjugate and the formation of a kit.

However, in view of the explicit suggestion in the reference to make the conjugate, it would have been obvious to one of ordinary skill in the art at the time of applicant's invention to make the claimed conjugate. The formation of a kit using known components is within the purview of one skilled in the art. Furthermore, since the compounds can be used in methods for diagnostic imaging and treating diseases, one of ordinary skilled in the art would immediately envisage that the compounds would need to be in pharmaceutically acceptable carriers.

With respect to the printed matter, the printed matter on a label or package insert does not lend patentable weight as a limitation of the claimed product, composition, or article of manufacture, absent a functional relationship between the label or package insert and the product, composition, or article of manufacture.

See In re Haller 73 USPQ 403 (CCPA 1947), where it is held that application of printed matter to old article cannot render the article patentable. In the opinion text of In re Haller, it is stated that: Whether the statement of intended use appears merely in the claim or in a label on the product is immaterial so far as the question of patentability is concerned...In accordance with the patent statutes, an article or composition of matter, in order to patentable, must not only be useful and involve invention, but must also be *new*. If there is no novelty in an article or composition itself, then a patent cannot be properly granted on the article or composition, regardless of the use for which it is intended. The difficulty is not that there can never be invention in discovering a new

process involving the use of an old article, but that the statues make no provision for patenting of an article or composition which is not, in and of itself, new.

Also see In re Venezia 189 USPQ 49 (CCPA 1976), where kits are drawn to the structural attributes of interrelated component parts and not to activities that may or may not occur. Further, In re Miller 164 USPQ 46 (CCPA 1969) and In re Gulak (CA FC)217 USPQ 401 relate to a mathematical device and to a measuring cup respectively. In each of these cases, the printed matter is considered a patentable distinction because the function of the device depends upon the printed matter itself which is a part of the substrate; without the printed indicia or numbers, the substrates lose their function. Such is not the case with the instantly claimed articles. The antibodies of the claimed articles remain fully functional absent the labeling or printed instructions for use.

It is further noted that the written material in the instructions is not considered to be within the statutory classes and does not carry patentable weight. See MPEP 706.03(a).

Response to applicant's arguments

Applicant argues that the newly added limitation ("at least one pharmaceutically acceptable excipient") overcome the prior art. As can be seen from the above rejection, each reference does meet this limitation.

Claims 22 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mercer-Smith et al in view of WO 93/21957. In view of the newly added limitation, the rejection is re-written.

Mercer-Smith et al disclose a conjugate comprising an antibody, porphyrins and Cu. On page 114, the reference discloses the administration of the conjugate to mice.

The only difference between the instant invention and the reference is that the instant invention uses Tc, Re or Mn as the radioactive metal and that the reference does not disclose the formation of a kit.

The WO document discloses that a variety of different radioactive metals can be used in conjugates and these include Cu, Tc, Re and Mn (see page 62).

In view of the WO document that states that any radioactive metal can be used, it would have been obvious to one of ordinary skill in the art at the time of applicant's invention to use Tc, Re or Mn instead of Cu in the primary reference. The formation of a kit using known components is within the purview of one skilled in the art. Furthermore, since the compounds are administered to mice, one of ordinary skilled in the art would immediately envisage that the compounds would need to be in pharmaceutically acceptable carriers.

With respect to the printed matter, the printed matter on a label or package insert does not lend patentable weight as a limitation of the claimed product, composition, or article of manufacture, absent a functional relationship between the label or package insert and the product, composition, or article of manufacture.

See In re Haller 73 USPQ 403 (CCPA 1947), where it is held that application of printed matter to old article cannot render the article patentable. In the opinion text of In re Haller, it is stated that: Whether the statement of intended use appears merely in the claim or in a label on the product is immaterial so far as the question of patentability is concerned...In accordance with the patent statutes, an article or composition of matter, in order to patentable, must not only be useful and involve invention, but must also be *new.* If there is no novelty in an article or composition itself, then a patent cannot be properly granted on the article or composition, regardless of the use for which it is intended. The difficulty is not that there can never be invention in discovering a new process involving the use of an old article, but that the statues make no provision for patenting of an article or composition which is not, in and of itself, new.

Also see In re Venezia 189 USPQ 49 (CCPA 1976), where kits are drawn to the structural attributes of interrelated component parts and not to activities that may or may not occur. Further, In re Miller 164 USPQ 46 (CCPA 1969) and In re Gulak (CA FC)217 USPQ 401 relate to a mathematical device and to a measuring cup respectively. In each of these cases, the printed matter is considered a patentable distinction because the function of the device depends upon the printed matter itself which is a part of the substrate; without the printed indicia or numbers, the substrates lose their function. Such is not the case with the instantly claimed articles. The antibodies of the claimed articles remain fully functional absent the labeling or printed instructions for use.

Response to Arguments

Applicant argues that the newly added limitation ("at least one pharmaceutically acceptable excipient") overcome the prior art. As can be seen from the above rejection, each reference does meet this limitation.

Claims 22 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 93/21957 in view of applicant's admission on pages 2-4 of the specification. In view of the newly added limitation, the rejection is re-written.

This reference discloses conjugates comprising a metal radionuclide ion(which can be Tc, Re and Mn) ,a complexing agent (which can be phenanthroline) and an immunoreactive group (which can be a variety of different antibodies, proteins, hormones etc) see pages 6, 8, 61-64.

The only difference between the reference and the instant invention, it that the reference does not specifically make the conjugate and the formation of a kit. The reference also does not disclose the other biomolecules and intercalating moieties claimed in claim 22 and 25.

On pages 2-4 of the specification, applicant admits that the other biomolecules and intercalating moieties are known in the art.

In view of the explicit suggestion in the reference to make the conjugate, it would have been obvious to one of ordinary skill in the art at the time of applicant's invention to make the claimed conjugate. It also would have been obvious to use any known biomolecule or intercalating agent. The formation of a kit using known components is within the purview of one skilled in the art. Furthermore, since the compounds can be

used in methods for diagnostic imaging and treating diseases, one of ordinary skilled in the art would immediately envisage that the compounds would need to be in pharmaceutically acceptable carriers.

With respect to the printed matter, the printed matter on a label or package insert does not lend patentable weight as a limitation of the claimed product, composition, or article of manufacture, absent a functional relationship between the label or package insert and the product, composition, or article of manufacture.

See In re Haller 73 USPQ 403 (CCPA 1947), where it is held that application of printed matter to old article cannot render the article patentable. In the opinion text of In re Haller, it is stated that: Whether the statement of intended use appears merely in the claim or in a label on the product is immaterial so far as the question of patentability is concerned...In accordance with the patent statutes, an article or composition of matter, in order to patentable, must not only be useful and involve invention, but must also be *new.* If there is no novelty in an article or composition itself, then a patent cannot be properly granted on the article or composition, regardless of the use for which it is intended. The difficulty is not that there can never be invention in discovering a new process involving the use of an old article, but that the statues make no provision for patenting of an article or composition which is not, in and of itself, new.

Also see In re Venezia 189 USPQ 49 (CCPA 1976), where kits are drawn to the structural attributes of interrelated component parts and not to activities that may or may not occur. Further, In re Miller 164 USPQ 46 (CCPA 1969) and In re Gulak (CA FC)217 USPQ 401 relate to a mathematical device and to a measuring cup

respectively. In each of these cases, the printed matter is considered a patentable distinction because the function of the device depends upon the printed matter itself which is a part of the substrate; without the printed indicia or numbers, the substrates lose their function. Such is not the case with the instantly claimed articles. The antibodies of the claimed articles remain fully functional absent the labeling or printed instructions for use.

Response to Arguments

Applicant argues that the newly added limitation ("at least one pharmaceutically acceptable excipient") overcome the prior art. As can be seen from the above rejection, each reference does meet this limitation.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheela J Huff whose telephone number is 703-305-7866. The examiner can normally be reached on Tuesday 5:30am-11:30am and Fridays 6:00am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Sheela J. Huff

Sheela J Huff
Primary Examiner
Art Unit 1642

sjh